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09/759,755	01/12/2001	Louis Brian Chapko	1369	4880

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

8

DATE MAILED: 08/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/759,755

Applicant(s)

CHAPKO ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 21-30, 34, 35, 37-43 and 47-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 2, 4-8, 21-27 and 40 is/are allowed.
- 6) ☒ Claim(s) 3, 9-16, 28-30, 34, 35, 37-39, 41-43, 47-49, and 50-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejections of claims 3, 5, 12, 12, 22, 24, 30-33, 40-44, and 47-49 under 35 U.S.C. 112, 2nd paragraph are withdrawn, in light of the claim amendments or cancellations.
3. The rejection of claims 13, 17, 32, 33, 36, 41, and 43 under 35 U.S.C. 102(e)/103(a) is withdrawn, in light of the claim amendments and further consideration.

Claim Rejections - 35 USC § 112

4. Claims 43 and 50-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 43: there is insufficient antecedent basis for the recitation, "The further PH7JD progeny maize plants or parts thereof".

In claims 50, 55, 60, 64, and 69: the recitation "A method of making a PH7JD plant" in line 1 of the claims renders them indefinite. However, the method cannot make a PH7JD plant, since it comprises introducing a gene into PH7JD. This plant is part of the starting material, not the product.

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In claims 53, 58, 62, 67, and 71: the recitation "comprising the method of claim 52 (or 50 or 55 or 60 or 64 or 69) and further comprising crossing the PH7JD maize plant of claim 52 with a second maize plant" renders the claim indefinite. If the method comprises crossing PH7JD with a second maize plant, it is not clear how the method of claim 52 is involved.

5. Claims 9-16, 28-30, 34, 35, 37-39, 41-43 and 47-49 remain and new claims 50-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 13 January 2003 under item 7. Applicant traverses the rejection in the paper filed 13 June 2003. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that the F1 hybrid seed and plant produced using PH7JD, regardless of the other maize plant used, is identifiable because it will have a single set of individual chromosomes coming from PH7JD. Applicants also argue that one would be able to run a molecular profile on PH7JD and the F1 hybrid to identify the hybrid as being produced from PH7JD (response, paragraph bridging pages 13-14, page 14, 1st full paragraph). However, as discussed in the previous Office action, no information is described about SSRs or other genetic markers of PH7JD. Further, the traits associated with any markers are not described.

Applicants argue that claim 14 has been amended to provide sufficient description to evaluate the presence of claimed traits (response, paragraph bridging pages 14-15). The claim

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has been amended to require the presence of all of the listed traits, rather than only "at least two." However, the specification does not describe any such claimed plants having all of the listed traits. Applicants argue that claims 15 and 16 are to a method of making a maize plant through the utilization of PH7JD, and that an old process performed with a novel material is novel in and of itself, and cite the Federal Register, Vol. 66, No. 4, in support (response, paragraph bridging pages 14-15). However, the method of claims 15 and 16 involved the utilization of descendants of PH7JD, which are not described. Methods are not described if products utilized in the methods are not described. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4.

Applicant also cites a prior art reference, Openshaw et al., for noting that, by using molecular markers, one may obtain 98% or greater genome identity between backcross conversion and recurrent parent after two backcrosses (response, paragraph bridging pages 14-15). However, Table 1 in the reference appears to indicate that only 87.5% of the recurrent parent genome is recovered after two backcrosses, and only assuming that there is no linkage to the gene being transferred. Further, the results referred to by Applicants were of computer simulations. Real field data showed that the recovery of the recurrent parent was lower after two backcross generations (page 42). Furthermore, the computer simulations of Openshaw et al. assume the absence of linkage of the allele being transferred from the donor parent. Moreover, even if 98% genome identity were obtained between the backcross conversion and recurrent parent, the remaining 2%, given the size of the maize genome, would encode traits not described by the specification. The specification also does not describe other nonselected traits and genes transferred during the first cross, and which are not selected out. Furtherstill, the instant disclosure did not describe any molecular marker data for PH7JD at the time of filing. Applicant

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cites Wych for teaching that the backcrossing has been used since the 1950s, and Poehman et al. for teaching that a backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene (response, paragraph bridging pages 15-16). However, neither reference indicates that the plant comprising the single gene conversion retains the traits of the recurrent parent that distinguishes it from other plants.

Regarding the position that the molecular profile of PH7JD is not described in the specification, Applicant argues that the specification describes that the seed deposit allows one of ordinary skill to run a molecular profile of PH7JD (response, page 16, 1st full paragraph). However, methods to obtain molecular markers do not describe the markers themselves. Applicants continue, arguing that an SSR profile is an inherent feature of inbred line PH7JD, and cite *Ex parte Marsili, Rosetti, and Pasqualucci* in support (response, page 16, 1st full paragraph). However, the issue in *Marsili* is not analogous. On page 905 of *Marsili*, the Court states that the amendment in *Marsili* was not new matter because it merely constituted a correction of a previously submitted description of a compound, which is permissible. Here, SSR would not merely be a correction of existing data, but would represent new characteristics. In *Marsili*, the specification disclosed a chemical structure for a compound, and the amendment merely corrected an error in the structure. In the instant case, no SSR data was present in the original specification, and introduction of such data would be new matter.

Applicants also argue that the test of written description is not whether the morphological and physiological traits of the PH7JD progeny are described, but whether subject matter was described in such a way to convey to one of ordinary skill in the art that the inventor had possession of the claimed invention. Applicants continue, arguing that while PVP is distinct

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from patents, the scope of protection conferred by PVP provides a clear indication that breeders of ordinary skill in the art consider mutations, F1 hybrids, backcross conversions, and transgenic conversions to be within the scope of the invention of the variety itself. The fact that the progeny have not been created does not prevent them from being protected in this manner (response, page 17, 1st paragraph). However, the originally filed specification only describes PH7JD by way of its morphological and physiological traits, and by way of deposit of PH7JD seed, not its genotype. As information concerning the genome of PH7JD was not known at the time of filing, molecular information cannot be used to describe progeny of PH7JD. Further, as Applicant admits, the requirements for PVP and patentability are distinct.

Regarding claims 37-39, Applicant argues that the claims are directed to growing out F1 hybrid in which PH7JD is a parent and searching for PH7JD inbred seed, and that the claim is described in the specification on pages 5-6 (response, page 17, 2nd full paragraph). However, as discussed above, the claims are included in the rejection because the method encompasses the use of products that are not described. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4.

Regarding new claims 50-73, Applicants argue that the claims are drawn to methods and to the products produced by those methods, and are further limited by specified traits conferred by mutant genes or transgenes, examples of which are in the specification on pages 21-35 (response, page 17, 3rd full paragraph and the paragraph bridging pages 17-18). However, the specification does not describe all mutant genes that confer the indicated traits. The specification also does not describe any maize plants having the introgressed gene, and which also have the morphological and physiological traits of PH7JD described in Table 1. Further, claim 47 does not place any limitation at all on the mutant gene or transgene, or that trait(s) affected by it.

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6. Claims 3 and 50-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed 13 January 2003 under item 8 for claims 18-20 and 47-49.

Applicants cancelled claims 18-20 and 47-49 in the paper submitted 13 June 2003.

However, the new claims have the same enablement issues as the cancelled claims.

Summary

7. Claims 1, 2, 4-8, 21-27, and 40 are allowed. Claims 3, 9-16, 28-30, 34, 35, 37-39, 41-43, 47-49, and 50-73 are rejected.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

August 26, 2003



Ashwin D. Mehta, Ph.D.
Primary Examiner
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